

March 2, 1999

The Honorable David M. Walker
Comptroller General of the United States
U.S. General Accounting Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Mr. Walker:

During the past several years, Internet use has evolved dramatically from a tool used mainly by research centers and universities to a powerful means of moving commerce available to millions of households. American consumers now use the Internet to purchase everything from airline tickets to investments to almost any item traditionally sold in a store.

One group of goods increasingly sold this way are pharmaceuticals. Companies reportedly selling pharmaceuticals online include "Thepillbox.com," "Drugstore.com," "Soma.com." and "PlanetRX.com." Ranging from both over-the-counter health aids to actual prescription drugs, many of these online pharmacy websites (also called "cybermedicine") now allow consumers using a home computer to purchase a range of pharmaceutical products once only available through a face-to-face visit with a doctor and a pharmacist. According to some press accounts, some Internet websites may even allow for a "virtual" doctor visit: medical information is submitted to a web-based drugstore, an online doctor reviews it and, based on that information decides whether to send a prescription directly to a customer's residence. This suggests that some web-based companies may be processing and delivering prescriptions for patients they have never seen, a medical practice some view as highly unethical and prone to serious problems.

A host of serious regulatory concerns are indeed raised by online pharmacies. For example, as patients are often required to submit highly sensitive and personal medical data to the online prescription company before their prescriptions are filled (or processed), it is unclear how effective each online company's methods are for safeguarding such information. Unlike losing a credit card number to an unscrupulous actor, misdirected or stolen personal medical information could have very serious long-term consequences for the consumer.

Others have suggested that online pharmacies could contribute to the problem of drug interactions, as the traditional face-to-face doctor-patient relationship is replaced by an online computer transaction. Although it appears that some online pharmacies require customers to fill out forms listing what other medications they are taking, or what other medical conditions they have, it is not clear that all firms require this, or how such a check of this information will ultimately be conducted. Finally, it remains murky how online pharmacies will process (if at all) controlled substances, and not be susceptible to abuse by hackers or other criminal elements. For example, if, as reported, some Internet pharmacies provide prescription drugs without requiring a patient to actually visit a doctor or pharmacist, certain controlled substances could be seriously susceptible to abuse.

In sum, we are concerned that the rapidly exploding trend of online pharmacies may be outpacing formal state and federal controls, and thus raising a host of serious issues. Given our concerns, we are requesting that the General Accounting Office (GAO) conduct a formal review of this area to determine the following:

(1) How pervasive is the online pharmaceutical industry? Please determine roughly how many online operations now exist, trends for this industry, and the dollar value in sales presently being conducted by online pharmacies.

(2) Please determine the differences between online pharmacies that presently operate over the Internet. For example, some reports suggest that most online pharmacies only fill prescriptions. Other reports, however, have suggested that some actually provide for a doctor consultation (for example, a quick questionnaire is submitted over the Internet, the doctor reviews it, and then the prescription can be approved and sent directly to the patient without a doctor ever seeing the patient). How prevalent is this latter operation? Do any trends appear in comparing one form of online pharmacy operation with another?

(3) Please determine how these firms are or are not being regulated by state and federal agencies. First, who are the primary regulators of online pharmacies at both the federal and state level? What are each of their responsibilities relative to online pharmacies? Are there serious jurisdictional gaps? If so, what are they, and what are their implications for the consumer? Second, what are existing regulators presently doing to oversee existing online pharmacies? What concerns have been reported? What issues do regulators see these firms as posing? As an example, can medical information be sold by one online pharmacy company to another? Third, do existing laws and regulations adequately apply to online pharmacy operations? If not, what are the discrepancies, and what changes, if any, may need to be made?

(4) How do these firms deal with issues such as medical records privacy/protection, the selling of controlled substances, or drug interactions? How serious are these issues and what shortcomings, if any, do online pharmacies have with regards to these issues? Also, how do online pharmacies prevent unqualified persons from receiving prescriptions? Are online pharmacies more susceptible to fraud or deception? If so, please explain how?

(5) What quality issues pertain to the methods used to ship these online pharmaceutical products? Do their actual sources need to be considered by state and federal regulators? If so, what are they and what are their implications for the consumer? Does the existing regulatory structure make it more difficult to guarantee quality, safety, and effectiveness? If not, why?

Thank you for your cooperation and attention to our request. If you have any additional questions about this matter, please have your staff contact Mr. Christopher Knauer of the Minority staff at (202) 226-3400. We look forward to working with you on this and other important pharmaceutical integrity and consumer protection issues.

Sincerely,

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